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	IFUF	II AMP	ON DIS	SCLOS	UHE CI	TATION	' <u>A'</u>	ATTY. DOCKET NO. PC25240A SERIAL NO. 10/763,340									
	(L	Jse se	veral si	neets if	necess	агу)	AP	PLICAN	T Tin	nothy A. H	agen, et al.						
										uary 23, 20	004	GRC)UP	1615			
L		<u> </u>					U.S	. PATEN	IL DOC	UMENTS							
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6	柳	us	5	1	6	9	6	4	5	12/8/92	Shukia, et a	ı.	424	499			
	\perp	us	5	66	3	3	0	0	6	5/27/97	Catania, et a	al.	424	441			
	1	us	5	6	0.	5	8	_ 8	9	2/25/97	Curatolo, et	<u>al.</u>	514	29			
<u> </u>	\perp	us	5	7	0	5	1	9	0_	1/6/98	Broad, et a	1	424	465			
<u> </u>	L	υs	5	7	4	7	0_	5	8	5/5/98	Tipton, et a	<u>. </u>	424	423			
	US 6 0 6 8							5	9	5/30/00	Curatolo, et	al.	424	490			
		US	_6	2	4	8	3	· 6	3	6/19/01	Patel, et al		424	497			
		us	6	5	0	0	_4_	5	9	12/31/02	Chhabra, et	al.	424	474			
Ш		υs	6	5	6	. 9	4	6	3	5/27/03	Patel, et al		424	497			
		US_	6	5	7	6	2	5	8	6/10/03	Koller, et a		424	458			
		us	_6	6	8	2	7	5	9	1/27/04	Lim, et al.		424	468			
	从	US	6	6	9	2	7	6	7	2/17/04	Burnside, et	al.	424	489			
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\coprod		wo	0	3	3_	7	3 `	0	4_	5/8/03	Internationa	ıi l	ABIK	9/16			
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	A			ОТН	ER DO	CUMEN	TS (Inc	duding A	uthor, 1	ītie, Date,	Pertinent Pa	ges, E	tc.)				
Ľ			Curato	olo, et al.,	US Pate	nt Applica	tion Publ	ication No	. US 2002	/0009433, A	pplication No. 09	788,8	88, Publis	hed 1/24/02			
1/4	8	\perp	Dunne	, U.S. Pa	itent Appl	ication Pu	blication	No. US 20	004/00238	198, Applicat	ion No. 10/628,1	02, Put	dished 2/5	5/04			

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	FILING DATE January 23, 2004	GROUP	1615
OTHER DOCL	JMENTS (Including Author, Title, Date,	Pertinent Pages, Et	c.)
Foulds, G., et al., "The effects of an a Feb; 31(2): 164-7 (Abstract)	untacid or cimetidine on the serum concentrations	of azithromycin*, J. Ciln.	Pharmacol, 1991
Amsden, G.W., et al., "Serum and Wi day period in healthy votunteers", J. /	BC pharmacokinetics of 1500 mg of azithromycin Antimicrobial Chemotherapy (2001), 47(1), 61-66	when given either as a s (Abstract)	Ingle dose or over
Zahremax azithremycin tablet 250 m	g, Quantitative Compecition of the Tablet Bland,	,	
Yahromax ezimromycin for orel susp	ension composition 200 mg/5mL, 200 mg/5mL Dr	up Product	
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Zithromax azithromycin for oral susp	zension composition 100 mg/5mL, Quantitative Co	empesitions of the Drug.	2roduct8
Zithromex [®] (exithromycin teblets and	azithromycin for oral suspension), Full U.S. Prese	eribing Information, 70-6	1 70-00-
Zahromes [®] (azithromyeln eapsules) (i 69.4763-69.9—	exithromyoin tablets) and (exithromyoin for oral su	(spension), Full U.S. Pro	scribing informatic
		rg Products with Therape	rotic Evaluations,
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	Foulds, G., et al., "The effects of an a Feb; 31(2): 164-7 (Abstract) Amsden, G.W., et al., "Serum and W day period in healthy volunteers", J. // Zihromax azithromycin tablet 250 m Zihromax azithromycin for oral suspension azithromycin for oral suspension expension (azithromycin teblets and Zihromax (azithromycin tablets azithromycin tablets and Zihromax (azithromycin tablets and azithromycin tablets and azithr	OTHER DOCUMENTS (Including Author, Title, Date, Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations Feb; 31(2): 164-7 (Abstract) Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin day period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 Zähromax azithromycin tablet 250 mg, Quantitative Composition of the Tablet Bland Zähromax azithromycin tor oral suspension composition 200 mg/5mt., 200 mg/5mt. De Zähromax azithromycin for oral suspension composition 1 gram sachet, Quantitative (Zähromax azithromycin for oral suspension composition 190 mg/5mt., Quantitative (Zähromax (azithromycin tablets and azithromycin for oral suspension), Full U.S. Press Zähromax (azithromycin eapsules) (azithromycin for oral suspension) Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Edition, Orange Book Listings of Azithromycin Dosage Forme	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc. Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azithromycin", J. Clin. Feb; 31(2): 164-7 (Abstract) Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin when given either as a siday period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 (Abstract) Zühremax azithromycin tablet 250 mg, Quantitative Compecition of the Tablet Bland Zühremax azithromycin for oral suspension composition 200 mg/5mt, 200 mg/5mt Brug Product Zühremax azithromycin for oral suspension composition 1 gram sachet, Quantitative Compecition of the Drugs Zühremax azithromycin for oral suspension composition 100 mg/5mt, Quantitative Compecitions of the Drugs Zühremax azithromycin teblets and azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61 Zühremax (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Presembing Information, 70-61

Conforms with FORM PTO-FB-A820

INFORMATION DISCLOSURE

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)
Page 1 of 7

ATTY. DOCKET NO. PC25240A

SERIAL NO.

10/763,340

APPLICANT Timothy A. Hagen, et al.

FILING DATE January 23, 2004

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	EXAMINE R INITIAL				DOC	UMENT NU				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
A	OH)	us	2	9	5	5	9	5	6	10/11/1960	Bauch et al	117	100	
	TY-										Baugh, et al.			
-	+	US	4	0	5	3	2	6	4	10/11/1977	King	425	8	
	+	US	4	0_	8	6	3	4	6	4/25/1978	Bocker, et al.	424	253	
	+	US	4	0	9_	2	0	8_	9	5/30/1978	Bocker, et al.	425	10	
	+-	US	4	2	9	3	5	7	0	10/06//1981	Vadasz	426	3	
	_	·US	4	4	7	4	7	6	8	10/02/1984	Bright	424	180	
	Д	US	4	5	1	7	3	5_	9_	05/14/1985	Kobrehel, et al.	536	7,4	
		us	4	6	7	5	1	4	0	06/23/1987	Sparks, et al.	264	4.3	
		US	4	8	7	4	6	1	1	10/17/1989	Wilson, et al.	424	410	
		US	4	9	3	1	2	8	5	06/05/1990	Edgren, et al.	424	473	
		US	4	9	5	7	6	8	1	09/18/1990	Klimesch, et al.	264	211.23	
I		US	4	9	6	3	5	3	1	10/16/1990	Remington, et al.	514	29	
		US	5	0	1	9	3	0	2					
I	1									05/28/1991	Sparks, et al.	264	8	
l	+	US	5	0	2	4	8	4	2	06/18/1991	Edgren, et al.	424	473	
	+	US	5	0	4	7	2	4	4	09/10/1991	Sanvordeker, et al.	424	435	
	\rightarrow	US	5	0	6	4	6	5	0	10/12/1991	Lew	424	435	
		US	5	0_	8	4	2	8	7	01/28/1992	Ghebre-Sellassie, et al	424	495	
		us	5	1	0	0	5	9	2	03/31/1992	Sparks, et al.	264	7	
		us	5	1	6	0	7	4	3	11/03/1992	Edgren, et al.	424	473	
		บร	5	1.	4	_3	6	6	2	09/1/1992	Chesterfield, et al.	264	8	
		US	5	1	8	3	6	9	0	02/02/1993	Carr, et al.	427	213.31	
		US	5	1	9	4	2 .	6	2	03/16/1993	Goldberg, et al.	424	401	
I		US	5	1	9	6	1	9	9	03/23/1993	Fulsz	424	401	
		US	5	2	1	3	8	1	0	05/25/1993	Steber	424	490	
Ì		US	5	2	3	6	7.					-		
-		US						3	4	08/17/1993	Fuisz	426	641	
ŀ	M		5	2	9	2	- 6	5	7	03/08/1994	Rutherford, et al.	435	243	
Ł	12.4	us	5	3	4	8	7	5	8	09/20/1994	Fuisz, et al.	426	660	

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION								ATTY.	. 10/76	53,340				
	6	Use s	everal s			ssary)	Į	APPLIC	ANT	Timothy A. I	lagen, et al.			
L	h/l		Pa	ge 2 of	<i>'</i>			FILING	DATE	January 23, 2	004	GROUP	1615	
K	P	us	5_	3_	8	0_	4	7	3	01/10/1995	Bogue, et a	1. 264	11	
L		us	5	4	0	5	6	1	7	04/11/1995	Gowan, Jr., e	t al. 424	464	
	\perp	us	5	4	0	7	6	7	6_	04/18/1995	Fuisz	424	401	
_	<u> </u>	us	5_	4	2	9	8	. з	6	07/04/1995	Fulsz	426	601	
_	_	US	5	4	3	3	9	5_	1	07/18/1995	Serajuddin, e	nt al 424	486	
_	L	us	5	4	5	6	9	3	2	10/10/1995	Fuisz, et a	426	548	
	<u>.</u>	us	5	5	4	9	9	1	7	08/27/1996	Cherukuri, el	al. 426	96	
_		us	5	4	6	11	0	8	9	10/24/1995	Handyside, e	t al. 523	171	
		US	5	5	0	0	1	6_	2	03/19/1996	Theisen, et	al 264	9	
Ц		US	5	5	0	1	8	5	8	03/26/1996	Fuisz	424	439	
Ц		US	5	5.	0	5	9	8	3	04/09/1996	Kamada	427	2.21	
		us	5	5	1	8	7	3	0	05/21/1996	Fuisz	424	426	
		us	5	5	3	9	0	0	0	07/23/1996	Leonard	514	682	
		us	5	5	4	9	9	1	7	08/27/1998	Cherukuri, et	al. 426	96	
Ц		US	5	5	5	6	6	5	2	09/17/1996	Cherukari, e	tal 426	5	
Ц		US	5	5_	6	9	4	6	7	10/29/1996	Ruiz	424	489	
Ц		us	5	5_	8	2	8	5	5	12/10/1996	Cherukuri	426	5	
		บร	5	5	9	7	4	<u>,</u>	6	01/28/1997	Fuisz, et al	. 127	30	×
Ц		US	_ 5	5	9	7	8	4	4	01/28/1997	Chauhan, et	al. 514	400	
		US	5	6	0	1	7	6_	_1	02/11/1997	Hoffman, et	al. 264	4.3	
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		us	5	-6	9	0	. 9	5	9	11/25/1997	Palepu, et a	il. 424	472	
Ц		us	5	7	0	7	6_	4	6	01/13/1998	Yajima, et a	ıl. 424	439	
Ц		us	5	7	3	3	5	7_	7	03/31/1998	Myers, et a	1. 424	488	
Ц		us	· 5	7	4	1	5	1	9	04/21/1998	Rosenberg, e	tal. 424	464	
\Box		us	5	7	4	4	1	8	0	08/28/1998	Cherukuri, et	al 426	99	
Ц	-0	us	5	7	6	6	5	2	1	06/16/1998	Le Thiesse et	al. 264	7	
Ø	W	US	5	7	٠ و	2	4	7	4	08/11/1998	Rauchfuss	424	489	

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AM	us	5	8	2	4	3	4	2	10/20/1998	Cherukuri, e	t al. 424	484			
1	us	5	В	4	0.	3	3	4	11/24/1998	Raiden, et	ai 424	464	>=		
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	US	5	В	5	1	5	5	3_	12/22/1998	Myers, et a	ni. 424	488			
	บร	5	8	5	1	5	5	5	12/22/1998	Sanghvi, et	al. 424	464			
	US	5	8	5	5	9	1	5	01/05/1999	Pinkus	242	486			
	US	5	8	6	9	0	9	8	02/09/1999	Misra, et a	1. 424	484			
	US	5	8_	6	9	1		1	02/09/1999	Moller, et a	al 424	489			
	US	5	8	8	3	1	0	3	03/16/1999	Bumside, et	al. 514	262			
	us	5	8	9	1	8	4	5	04/06/1999	Myers	514	11			
	us	5	9	1	2	0	3	0	06/15/1999	Huzinec, et	al. 426	3			
	us	5	9	1	9	4	8	9	07/06/1999	Saleki-Gerhard	t, et al. 424	501			
	US	5	9	3	5	6	0	.0	08/10/1999	Cherukuri, e	t al. 424	464			
	US	5	9	4	8	4		7	09/07/1999	McGuinness,	et al. 424	184.1			
	us	5	9	5	. 2	0	0	4	09/14/1999	Rudnic, et	BI. 424	455			
	US	5	9	5	8	4	5	2	09/28/1999	Oshlack, et	al. 424	457			
	บร	5_	9_	6	5	1	8	1	10/12/1999	Oshlack, et	al. 424	457			
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	US	5	9	7	2	3	7	3	10/26/1999	Yajima, et	al. 424	439			
	US	5	9	8	0	9	4	1	11/09/1999	Raiden, et	el. 424	464			
	US	.6	0	1	0	7	1	8	01/04/2000	A⊩Razzak, e		464			
	us	6	0	1	3	2	8	0	01/11/2000	Frisbee, et		464			
	us	6	0	4	8	5	4	1	04/11/2000	Mirsa, et a		401			
	us	6	0	5	1	2	5	3	04/18/2000	Zettler, et a		465			
	us	66	0	7	7	5_	4	1	06/20/2000	Chen, et a	1. 424	480.			
1	us	66	0	8	3	4	3	_0_	07/04/2000	Fulsz, et a	1. 264	5			
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DA	us	6	1	0	3	2	6	4	08/15/2000	Hoffmann, e	t al.	424	468		
0.	us	.6	1	1	7	4	5	2	09/12/2000	Ahlgren, et	al.	424	468		
	US	6	1	3	9	8	7	2	10/31/2000	Walsh		424	464	<u>-</u>	
	US	6	1	6	5	5	1	2	12/26/2000	Mezaache, e	t al.	424	489		
	US	6	2	2 .	1	3	6	8	04/21/2001	Breitenbach,	et al.	424	400		
	US	6	2	6	1	5	9	9	07/17/2001	Oshlack, et	al.	424	457		
	US	6	2	6	8	4	8	9	07/31/2001	Allen, et a	J	536	7.4		
	us	6	2	7	0	8	0	4	08/07/2001	Getz, et a	i	424	490		
	US	6	3	2	8	9	9	3	12/11/2001	Linder, et	al	.424	451		
	US	6	3	3	5	0	3	3	01/01/2002	Oshlack, et		424	457		
	US	- 6	3	8	3	5	1	0	05/07/2002	Linder, et		424	436		
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	US	6	5	5	1	6	1	6	04/22/2003	Notario, et		424	464		
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	2001	೦	0	0	6	6	5	Ö	7/01	Burnsida, e	<u> </u>	424	400		
	2002	0	0	0	9	4	3	3	1/02	Curatilo, e	3	424	94:1		
	2002	0	0	2	5	3	4	2	02/28/2002	Linder, et		424	489		
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	2005	0	0	2	6	8	5	1	02/03/2005	Danilovski, e		514	28		
	US	5	6	0	5	8	8	9	02/25/1997	Curatolo, et		514	29		
	2003	0	2	2	8	3	5	7	12/11/2003	Johnson, et		424	465		
1	2003	0	1	6	5	5	6	3	09/04/2003	Murphy, et		424	465		
T	2003	0_	,	9	0	3	6	5	10/09/2003	Fergione, e		424	489		
	US	4	9	6	3	5	3	1	10/16/1990	Remingto		514	29		
	2004	0	0	1	4	9	5	1	01/22/2004	Dumic et		536	7.1		
	us	6	3	6	5	5	7	4	04/02/2002	Singer et a		514	29		
	US	6	2	. 4	5	9	0	3	06/12/2001	Karlmian, e		536	7.4		
N	2004	0	1	2	1	0	0	3	06/24/2004	Chickering, III		424	465		

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PH	us	6	6	8	9	3_	9	0		02/10/2004	Bernstein, e	al. 424	501		
.	US	6	4	2	3	3	4	5		07/23/2002	Bernstein, e	al. 424	501		
M	US	6	6	4	5	5	2	8		11/11/2003	Straub, Ket	al. 424	489		
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	wo	9	1	0	7	1		, [1	30 May 91	Internation	al A61K	9/16		
	wo	9	4	0		1			2	06 Jan 94	Internation	al A61K	9/22		
	wo	9	4	2	7	5		,	7_	8 Dec 94	Internation	al A81			
	wo	9	8	0	6	7	1		4	19 Feb 98	Internation	al C070	311/74		
	wo	9	8	4	6	2	3	3	9	22 Oct 98	Internation	al A61K	31/71		
	wo	9	9	_0	3	4	5	<u>.</u>	_ 3	28 Jan 99	Internation	al A61K	9/50		
	wo	9	9	2	4	. 0	3		1	20 May 99	Internation	al A61K	31/40		
	wo	0	0	2	6	2		3	5	11 May 00	Internation	al C08k	5/103		
	wo	0	0	5	7	8	8		6	05 Oct 00	Internation	al A61K	31/70		
	wo	o	1	4	2	2			1	14 Jun 01	Internation	al CO70	231/12		
	wo	0	1	7	8	6	8		8	25 Oct 01	Internation	al A61K	9/24		
	wo	0	1	8	5	1	3		5	15 Nov 01	Internation	al A61K	9/00		
<u>.</u>	wo	0	2	2	4	1	7	,	4	28 Mar 02	Internation	al A61K	6/50		
	wo	4	0	3	5	0	6		3	29 Apr 04	Internation				
	wo	3	0	3	2	9	2		2	24 Apr 03	Internation				
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	wo	4	0	8	7	0	8		6	14 Oct 04	Internation				
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DIFORMATION DISCLOSURE





Patent Application Attorney Docket No.PC25240A EXPRESS MAIL NO. EV635919223US

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in an en	velope addressed to: Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313 on this 5th day of August, 2005.
Ву	Danna LShidds
	(Signature of person mailing)

Deanna L. Shields

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Timothy A. Hagen, et al.

APPLICATION NO.: 10/763,340 : Examiner: Pili Asabi Hawes

FILING DATE: January 23, 2004 : Group Art Unit: 1615

TITLE: AZITHROMYCIN DOSAGE FORMS WITH

REDUCED SIDE EFFECTS

Mail Stop AF Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

RESPONSE TO FINAL OFFICE ACTION

In full response to the final Office Action mailed July 22, 2005, Applicants respectfully present the following remarks.

A response to the July 22, 2005 Office Action is due prior to October 22, 2005. Therefore, the present Response is being timely filed.

0 K to Enter PH 8/19/2005